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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/014,338	12/10/2001	Herath Mudiyanseilage Athula Chandrasiri Herath	9195-077	1523

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EXAMINER

TURNER, SHARON L

ART UNIT PAPER NUMBER

1647

DATE MAILED: 09/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<p align="center">Office Action Summary</p>	Application No. 10/014,338	Applicant(s) HERATH ET AL.	
	Examiner Sharon L. Turner	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 7-9, 24-26 and 30-32 is/are pending in the application.
- 4a) Of the above claim(s) 7-9 and 30-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 24-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-3, 7-9, 24-26 and 30-32 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9-25-02, 10-8-02</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The amendment filed 7-6-04 has been entered into the record and has been fully considered.
2. Claims 1-3, 7-9, 24-26, and 30-32 are pending.
3. The utility of SEQ ID NO:2 is noted in the art to correspond to a tricarboxylate (citrate) carrier protein as noted in Azzi et al., 1993 (IDS) and is recognized as such as set forth in this specification and the prior art of record. SEQ ID NO:2 differs by only 14 amino acids, 8 of which are conservative substitutions amongst the members. The sequences of Azzi and SEQ ID NO:2 are thus 95.8% identical. The prior art also notes a rat tricarboxylate carrier as disclosed in WO 01/38369 (IDS) whose sequence is 99.6 % identical to instant SEQ ID NO:2, differing at only a single amino acid residue. The priority date of this reference extends to 22 November 1999 and the reference designated the United States, but the reference was published in Japanese and therefore is not eligible as prior art under 102(e). No other publications related to this document are believed to be available as prior art.

Election/Restrictions

4. Applicant's election with traverse of Group I, polypeptide, and SEQ ID NO:2 in the reply filed on 3-12-04 and 7-6-04 is acknowledged. The traversal is on the ground(s) that SEQ ID NO:2 is related to SEQ ID NO:4 in that it is a splice variant and shares sequence similarity within residues 1-198 of the 322 and 252 amino acid forms and that as such there is no burden for search and examination in a single case. Applicant's also refer to MPEP 803.04 noting the ability to waive the requirement for

restriction where no burden is present. This is not found persuasive because as previously set forth the inventions are distinct in that the different sequences are drawn to different residues and require different and non-coextensive searches. The different structures further do not necessarily share the same function, utility, enablement or relevance to prior art. Thus, serious search burden arises in both the search and examination of the non-coextensive sequences.

The requirement is still deemed proper and is therefore made FINAL.

5. Claims 7-9, and 30-32 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 3-12-04 and 7-6-04.

Specification

6. The disclosure is objected to because of the following informalities: The views are not appropriately labeled within the Brief Description of the Drawings, i.e., Figures 2A-2B, 3A-3B.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

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only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1-2, and 24-26 are rejected under 35 U.S.C. 102(e) as being anticipated by Tang et al., WO 01/53312, 26 July 2001, with priority date of at least 29 November 2000 based upon 09/727,344, see in particular SEQ ID NO:4.

Tang et al., teach novel nucleic acids encoding a polypeptide corresponding with 100% similarity to instant SEQ ID NO:2, see in particular Tang SEQ ID NO:3558. Also encompassed are variants and fragments of the peptides as well as fusion proteins, see in particular p. 18, lines 1-4 and 4.6, pp. 27-32 and 4.7, 32-34. Pharmaceutical formulations are noted in particular throughout, see in particular 4.12, pp. 63-73. Antibodies generated from immunogenic preparations with adjuvants are noted throughout 4.13, pp. 74-84. A vaccine preparation is recognized in the art as one that is immunogenic and stimulates a protective immune response in the host. As noted above, the reference teachings as to pharmaceutical preparations with peptide and adjuvant would therefore anticipate the recitation as to a vaccine formulation. Moreover, the reference notes that the formulations of the invention may be used as immune stimulating compositions, see in particular pp. 46-50 and specifically for treatment of infectious diseases as noted at p. 46, lines 29-32. Thus, the reference teachings anticipate the claimed.

9. Claims 1-2 are rejected under 35 U.S.C. 102(e) as being anticipated by Attersand et al., WO 02/42324, 30 May 2002, with priority date of 24 November 2000.

Attersand et al., teach gene encoding protein cluster I and the encoded protein sharing 100% sequence identity with instant SEQ ID NO:2, see in particular Attersand

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SEQ ID NO:8. The reference further describes other protein cluster I variants that are modified by one or more amino acids, see in particular abstract and sequences 1-6 and p. 4-6 which may be linked or fused to reporter sequences, see for example p. 7. The linked polypeptides with reporter constructs constitute fusion proteins and thus anticipates fusion polypeptides. Therefore, the reference teachings anticipate the claimed invention.

10. Claims 1-3, and 24-26 are rejected under 35 U.S.C. 102(e) as being anticipated by Reddy et al., WO 01/77174, 18 October 2001 (IDS), with priority date of at least 12 April 2000 based upon 60/196,872, see in particular SEQ ID NO:2.

Reddy teaches SEQ ID NO:2 identified as a human transporter ion channel corresponding with 100% identity to instant SEQ ID NO:2. The invention includes related molecules with one or more modified amino acids, fragments and specifically immunogenic fragments, see in particular pp. 12-13, and 21-22. Further, the invention is directed to antibodies and immunogenic fragments, pp. 26. Reddy teaches placement of marker genes in tandem with the TRICH sequences under control of a single promoter. Such constructs are recognized as fusion peptides where a portion of the molecule is TRICH and another portion is the marker gene and the sequences are produced together for marking expression. In particular, the reference notes that suitable marker proteins that are visible and may be so linked includes green fluorescent protein, see in particular pp. 39, line 34-p. 40, line 20. Pharmaceutical preparations for treating diseases, including infectious disease are noted at pp. 44-47 with suitable adjuvants as noted at pp. 47, lines 14-20. Thus, the reference teachings

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anticipate vaccine preparations with adjuvant. Therefore the reference teachings anticipate the claimed invention.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tang et al., WO 01/53312, 26 July 2001, Attersand et al., WO 02/42324, 30 May 2002, and Reddy et al., WO 01/77174, 18 October 2001.

Tang and Attersand are as set forth above.

Neither Tang and Attersand teach a fusion polypeptide of SEQ ID NO:2, a modified form of SEQ ID NO:2 or fragment of SEQ ID NO:2 with green fluorescent protein.

However, both Tang and Attersand teach the desirability of fusion constructs linked to suitable reporter or selection molecules whereby expression may be monitored, see in particular Tang, p. 19 and Attersand, p. 7.

Reddy notes Reddy teaches placement of marker genes in tandem with sequences of SEQ ID NO:2 under control of a single promoter expressed as fusion peptides where the selectable marker gene is visible via expression of green fluorescent protein, see in particular pp. 39, line 34-p. 40, line 20.

Thus, one of skill in the art would be motivated to provide fusion of the SEQ ID NO:2 sequences with green fluorescent protein to provide for selection and moreover would be motivated to use the selectable marker green fluorescent protein given its advantage in that the marker is easily detected via visibility without the need for further assay or enzymatic testing. One would expect such success as Reddy teaches that the green fluorescent protein provides for the advantage of a selectable marker that is visible. Thus, the reference teachings anticipate the claimed invention.

Conclusion

13. No claims are allowed.

14. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

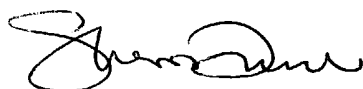
Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Turner, Ph.D. whose telephone number is (571) 272-0894. The examiner can normally be reached on Monday-Friday from 8:00 AM to 4:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached at (571) 272-0961.



SHARON L. TURNER, PH.D.

PATENT EXAMINER

9-20-04

Sharon L. Turner, Ph.D.
September 20, 2004